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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,800	01/15/2002	Betty Rozier	TBA	7638

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EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/046,800	Applicant(s) ROZIER ET AL.	
	Examiner Kathryn Odland	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 2-30 and 37-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 31-36, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>23 April 2002</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment*

This is a response to the amendment dated October 4, 2004. Claims 1-56 are pending. Claims 1, 31-36 and 54-55 are under consideration and claims 2-30 and 37-54 have been withdrawn from consideration. The terminal disclaimer is acknowledged. The objection to the drawing is withdrawn. However, element 31 is discussed in reference to the embodiment of figure 19 but not shown in that embodiment. The initialed IDS citations are included in this action.

### *Response to Arguments*

1. Applicant's arguments filed October 4, 2004 have been fully considered but they are not persuasive.

It appears that applicant is taking an extraordinarily narrow interpretation of the claims. Claim 1 recites the limitation:

A **hollow** member having a base, the base having an edge to be positioned upon a patient **adjacent a site**, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site.

Hollow is defined as having a cavity, gap, or space within according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Adjacent is defined as close to lying near according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Thus, this limitation is extremely broad requiring a

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member with a cavity or gap having a base with an edge to be positioned "near" a site.

The base straddles the site and has a length sufficient to cover the site.

Regarding applicant's arguments for the rejection under 35 U.S.C. 102(b), applicant argues, "Consequently, Grant cannot anticipate claim 1 because Grant does not disclose a hollow member with a base having an edge to be positioned upon the body part of a patient adjacent to a site." However, the examiner respectfully disagrees. The device of Grant has a hollow member (such as 16 and associated components). The base 16 has walls 24 and 26. Thus, there is a cavity or gap or space within, as seen in figure 2. Therefore, the member can be considered hollow. The base is the bottom portion (@ numbers 12/16). The base has an edge (any of the edges or sides) to be positioned upon a patient near a site. This phrase, it extremely broad, for adjacent simply means near, so something that is positioned above, below or to the side can be considered adjacent and would depend upon a point of reference. Moreover, this limitation is also dependent upon where the "site" is located. A type of site or location of a site has not been established. Thus, given this broad limitation the base has a width sufficient to straddle the site and a length and a height sufficient to cover the site. Broadly it can straddle above, below or to the side of the site. It is not positively recited that the base covers the site; it is merely of sufficient height to cover the site. Moreover, given the broad limitation which direction it covers the site is not limited. The prior rejection is reiterated below.

Regarding applicant's arguments for the rejection under 35 U.S.C. 103(a), applicant argues limitations that are not claimed. Darling discloses the connector with

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pad 11 to cover an IV site. Darling does not recite a hollow member having a base.

However, Grant teaches a hollow member with a base (14) to cover the IV site. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Darling to replace the pad 11 by a rigid hollow member as taught by Grant. The motivation for this combination can be found in column 1 of Grant, which discusses inadequate retention of the cannula/IV.

Applicant has failed to claim structural limitations to define over the prior rejection. Thus, the rejection is reiterated below.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Grant in US Patent No. 5,413,120.

Regarding claim 1, Grant discloses a site guard having a hollow member having a base (such as 16 with associated components), *the base having an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover* (such as with or without 14); at least one fabric connector (such as 48, 40, etc) affixed to the hollow member; means (via Velcro® and associated components and slits) for affixing the hollow member to the at least one fabric

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connector; and means (via Velcro®) for closing the fabric connector on the patient, as recited in columns 2-4 and seen in figures 1-3. That shown in italics above is considered functional language. Nonetheless, the device of Grant performs and is capable of performing the function.

4. Claim 55 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Gamble in US Patent No. 849,471.

Regarding claims 55 and 56, Gamble discloses a hollow member (generally @ 4) having a base (7) with an edge to be positioned upon a patient adjacent a site and a length and a height sufficient to cover the site, as recited throughout the specification. The base (7) is joined to a sidewall to form a cover. There is a fabric (inherent as ordinary – lines 45-50) connector (11) having closure means capable of holding the hollow member in place over the site without the need for adhesive tape. The first end is affixed to the hollow member and the second end has means to attach. Applicant's closure means is extremely broad enough to include any type of attachment, as recited on page 13 of the instant application.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 1 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darling in US Patent No. 5,076,289 in view of Grant in US Patent No. 5,413,120.

Regarding claim 1, Darling discloses a site guard having at least one fabric connector (shown generally at 10); a pad (11); and means (via Velcro®) for closing the fabric connector on the patient, as recited in columns 2-4 and seen in figures 1-2F.

However, Darling does not show a hollow member having a base, the *base having an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover* where the fabric member is affixed to the hollow member and means for affixing the hollow member to at least one fabric connector. On the other hand, Grant teaches a hollow member (such as 14). Therefore, it would be obvious to one with ordinary skill in the art to replace the pad (11) of Darling with a hollow member for the purpose of having the IV site closer to the hand while maintaining proper security. This combination would yield a *base having an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover* where the fabric member is affixed to the hollow member and means for affixing the hollow member to at least one fabric connector. Further, that shown in italics is considered functional language. Nonetheless, the combination would be capable of performing the function.

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Regarding claim 31, Darling as modified by Grant discloses that as applied to claim 1, as well as, at least one fabric connector further having at least one opening (13, 14) to accommodate various body parts, as seen in figures 1-2F.

Regarding claim 32, Darling as modified by Grant discloses that as applied to claim 31, as well as, at least one fabric connector having a first opening and a second opening configured to ambidextrously accommodate one or more digits, as seen in figures 1-2F.

Regarding claim 33, Darling as modified by Grant discloses that as applied to claim 32, as well as, a first opening that is configured to receive the right thumb and the second opening is configured to receive the left thumb, wherein either thumb can be inserted in the device.

Regarding claim 34, Darling as modified by Grant discloses that as applied to claim 1, as well as, a Velcro ONE-WRAP strap, and/or combinations of any of the foregoing, as recited in columns 2-4.

Regarding claim 35, Darling as modified by Grant discloses that as applied to claim 34. Further, this combination would yield a Velcro ONE-WRAP strap that affixes to affixing means on the sidewall of the hollow member.



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Regarding claim 36, Darling as modified by Grant discloses that as applied to claim 34, as well as, at least one opening to accommodate various body parts, as recited in column 2-4 and seen in figures 1-2F. Further, the tubular mesh is considered an equivalent to a Velcro ONE-WRAP.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

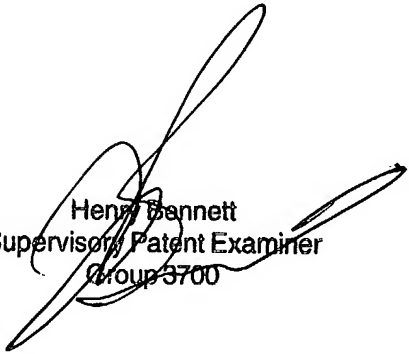
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (571) 272-4801. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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